K120271

MAY 30 2012

ARTISAN™ Space Maintenance System
510(k) Summary

Below is the 510(k) summary submitted to the FDA containing information per Code of Federal Regulations, Title 21, Part 807.92; This 510(K) is submitted for one reason: to provide appropriate MRI labeling for the subject devices, while also providing MRI technologists with a method of concluding whether an MRI scan can be performed on the device and specific instructions on how to perform the scan.

I. Submitter Information

Sponsor: Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132

Contact Person: Lin Wu, Regulatory Affairs Specialist
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(901) 396-3133

Date Prepared: April 18, 2012

II. Device Name

Proprietary Trade Name: ARTISAN™ Space Maintenance System
Common/Usual Names:
Classification Name: Bone Plate (Regulation Number 21 CFR 872.4760)
Product Code: JEY, DZE

III. Predicate Devices

ARCHITEX™ Space Maintenance System (K100779 SE 12/13/2010, and K110259 SE 04/13/2011)

IV. Device Description

The ARTISAN™ Space Maintenance System is a comprehensive, all-inclusive system which contains a variety of implants designed to temporarily reconstruct bony deficiencies common to the oral cavity that are not intrinsic to the stability of the bony structure. Bony deficiencies

may be naturally occurring osseous defects, surgically created osseous defects, or osseous defects created from traumatic injury to the bone.

The ARTISAN™ Space Maintenance System includes a selection of Socket Preservation screws which are designed to aid in extraction socket grafting while simultaneously supporting the original gingival margins and papilla. The system contains a porous titanium mesh (with only one size of 76mm x 44mm x 0.2mm), titanium alloy mesh fixation screws (with sizes of 1.2mm or major diameters x 4mm or 6mm or 8mm or 10mm or 12mm or 14mm lengths, and with sizes of 1.4mm major diameters x 3mm or 5mm or 7mm lengths), titanium alloy tenting screws (with sizes of 1.2mm or 1.4mm major diameters x 8mm or 10mm or 12mm or 14mm lengths x 5mm head diameter), and titanium alloy socket preservation screws (with sizes of 1.2mm or 1.4mm major diameters x 14mm or 18mm or 20mm lengths x 3/4mm or 4/5mm or 5/6mm head diameters). When used as indicated, this system provides a semi-protected space to stabilize, support, and protect bone graft (autograft, autograft extenders, allograft, and bone void fillers) by minimizing soft-tissue collapse into the graft recipient site.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy, and medical grade cobaltchromium-molybdenum alloy may be used together.

Technological Characteristics

The ARTISAN™ Space Maintenance System has the same design, same materials, and physical properties as their respective predicate devices, and is substantially equivalent to their predicate devices.

V. Indications for Use

The ARTISAN™ Space Maintenance System is indicated for use as temporary implants to stabilize and support autograft, autograft extenders, allograft, and bone void fillers and/or fractured bone segments with or without bone plates or titanium mesh in bony defects of oral maxillofacial anatomy.

The ARTISAN™ Space Maintenance System is intended for temporary use in oral maxillofacial surgical reconstruction and dental regeneration procedures for maintaining space during bone grafting procedures and to support soft tissue until bone formation.

The ARTISAN™ Space Maintenance System has the same indications for use as their respective predicate devices.

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VI. General discussion of the non-clinical tests submitted

For a determination of substantial equivalence, the following analyses and bench performance tests were performed on Subject Devices and Predicate Devices: h

- Analysis of Dimensional and Material Features
- Static Axial Pullout Testing in accordance with ASTM F543-02;
- Static Subsidence Testing (to date there are no industry standards);
- Static Cantilever Bending Testing (to date there are no industry standards);
- Static "Removal Torque" and "Torque to Failure" testing in accordance with ASTM F543-02

For a determination of MRI labeling and safety information, the following analyses and bench tests were performed on the Subject Devices:

- Magnetic Field Interaction Evaluation at 3-Tesla (ASTM F2052-06)
- Qualitative Torque Assessment (ASTM F2213-06)
- MRI related Heating Assessment at 1.5-Resla and 3-Tesla (ASTM F2182-11)
- Artifact Assessment at 3-Tesla (ASTM F2119-07)

VII. Conclusions drawn from the non-clinical Tests

Results of the MRI testing have demonstrated that the ARTISAN™ Space Maintenance System can be classified as MR-Conditional in 1.5 and 3 Tesla environments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Lin Wu
Regulatory Affairs Specialist
Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

MAY 30 2012

Re: K120271
Trade/Device Name: ARTISAN™ SPACE MAINTENANCE SYSTEM
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZE
Dated: May 24, 2012
Received: May 24, 2012

Dear Mr. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known):

Device Name: ARTISAN™ SPACE MAINTENANCE SYSTEM

INDICATIONS FOR USE:

The ARTISAN™ Space Maintenance System is indicated for use as temporary implants to stabilize and support autograft, autograft extenders, allograft, and bone void fillers and/or fractured bone segments with or without bone plates or titanium mesh in bony defects of oral maxillofacial anatomy.

The ARTISAN™ Space Maintenance System is intended for temporary use in oral maxillofacial surgical reconstruction and dental regeneration procedures for maintaining space during bone grafting procedures and to support soft tissue until bone formation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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